

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 414/04400	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/IL2005/000135	International filing date (day/month/year) 04.02.2005	Priority date (day/month/year) 05.02.2004	
International Patent Classification (IPC) or national classification and IPC A61N1/00			
Applicant REABILITY INC. et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> <i>(sent to the applicant and to the International Bureau)</i> a total of 6 sheets, as follows:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application 			
Date of submission of the demand 05.12.2005	Date of completion of this report 23.01.2006		
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Kempin, H-F Telephone No. +49 89 2399-2716		



**INTERNATIONAL PRELIMINARY REPORT
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International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-20 as originally filed

Claims, Numbers

1-48 filed with telefax on 05.12.2005

Drawings, Sheets

1/5-5/5 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:

- the description, pages
- the claims, Nos.
- the drawings, sheets/figs
- the sequence listing (*specify*):
- any table(s) related to sequence listing (*specify*):

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages
- the claims, Nos.
- the drawings, sheets/figs
- the sequence listing (*specify*):
- any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
 - the entire international application,
 - claims Nos. 36-46,48
because:
 - the said international application, or the said claims Nos. 36-46,48 relate to the following subject matter which does not require an international preliminary examination (specify):
see separate sheet
 - the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - no international search report has been established for the said claims Nos. 36-46
 - the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	<input type="checkbox"/> has not been furnished
	<input type="checkbox"/> does not comply with the standard
the computer readable form	<input type="checkbox"/> has not been furnished
	<input type="checkbox"/> does not comply with the standard
- the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-35,47
	No: Claims	
Inventive step (IS)	Yes: Claims	1-35,47
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-35,47
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 36-46 and 48 relate to a method for treatment of the human or animal body by therapy. According to Rule 67.1(iv) PCT an International Preliminary Examining Authority is not required to carry out an examination for that kind of claim.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO-A-02/092164

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1 and shows (the references in parentheses applying to this document):

Apparatus for rehabilitating a patient who has a paretic body part, the apparatus comprising:

a) at least one electromyography EMG sensor adapted to being applied to a voluntary muscle of a healthy body part of the same type as the paretic body part, which at least one sensor produces at least one EMG signal (see the last paragraph on page 19);

b) a neuromuscular electrical stimulation NMES device adapted for stimulating at least one voluntary muscle of the paretic body part (see the paragraph bridging pages 17 and 18); and

c) a controller which controls the NMES device, said controller being configured to:

I) store a desired motion of said paretic body part (see 31 in figure 4 and page 20, paragraph 4).

The subject-matter of claim 1 differs from this known apparatus by features ii) and iii).

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as to improve the known apparatus so that it encourages the development of alternate pathways for nerve

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impulses in the patient, or alternate locations in the motor cortex to originate nerve impulses to the muscles.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
There is no incitation in the available prior art to store in the controller NMES amplitude insufficient to cause said desired motion and to determine an amplitude of stimulation such that said NMES stimulation is not sufficient, on its own, to move said paretic body part with said desired motion.

Claims 2-30 and 47 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Independent claim 31 includes in substance the essential distinguishing features of claim 1 (NMES amplitude insufficient to cause, on its own, desired motion but ...) and is considered new and inventive for the same reasons as claim 1. Dependent on claims 32-35 and 47 thus also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VIII

Certain observations on the international application

1. Although claims 1 and 31 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

2. The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

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3. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

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CLAIMS

1. Apparatus for rehabilitating a patient who has a paretic body part, the apparatus comprising:

5 a) at least one electromyography (EMG) sensor adapted to being applied to a voluntary muscle of a healthy body part of the same type as the paretic body part, which at least one sensor produces at least one EMG signal;

b) a neuromuscular electrical stimulation (NMES) device adapted for stimulating at least one voluntary muscle of the paretic body part;

10 c) a controller which controls the NMES device, said controller being configured to:

(i) store a desired motion of the paretic body part,

(ii) store NMES amplitude insufficient to cause said desired motion; and

(iii) determine an amplitude of stimulation of the paretic body part at least partly based on the EMG signal from the healthy body part and said storage such that said NMES stimulation is not sufficient, on its own, to move said paretic body part said desired motion.

20 2. Apparatus according to claim 1, wherein the at least one muscle of the healthy body part corresponds to the at least one muscle of the paretic body part.

3. Apparatus according to claim 1, wherein said controller is configured to process said EMG signals and determine at least one property of said NMES signal.

25 4. Apparatus according to claim 2, wherein the controller is configured so that the NMES stimulates the paretic body part to make a movement corresponding to a movement made by the healthy body part when the EMG signals are sensed.

30 5. Apparatus according to claim 4, wherein the controller is configured so that the amplitude of stimulation of at least one of the at least one muscle of the paretic body part increases when the EMG signal from the corresponding muscle of the healthy body part increases at a corresponding time in the movement of the healthy body part.

6. Apparatus according to claim 4 or claim 5, wherein the at least one muscle of the paretic body part comprises an antagonistic pair of muscles, and the controller is configured so

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that the amplitude of stimulation of one muscle of the antagonistic pair of muscles decreases when the EMG signal from the muscle in the healthy body part corresponding to the other muscle of the antagonistic pair of muscles increases at a corresponding time in the movement of the healthy body part.

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7. Apparatus according to any of the preceding claims, wherein one or both of the controller and the NMES device are configured to store a stimulation amplitude that is not high enough to cause the stimulated muscle to contract in the absence of nerve impulses from the patient's brain, but is high enough to cause the muscle to contract in the presence of nerve impulses from the patient's brain, for at least some patients who cannot move said body part by themselves.

8. Apparatus according to any of the preceding claims, wherein the at least one EMG sensor comprises a plurality of EMG sensors, each EMG sensor adapted to being applied to a different muscle or muscle part of the healthy body part.

9. Apparatus according to claim 8, wherein each EMG sensor produces a separate EMG signal.

20 10. Apparatus according to claim 9, wherein the NMES device is adapted to independently stimulate a plurality of muscles or muscle parts of the paretic body part.

11. Apparatus according to claim 10, wherein said plurality of muscles or muscle parts of the paretic body part correspond to the muscles or muscle parts of the healthy body part to 25 which the plurality of EMG sensors are adapted to being applied.

12. Apparatus according to claim 11, wherein the controller is configured so that amplitude of NMES stimulation of said plurality of muscles or muscle parts of the paretic body part is at least partly dependent on the EMG signals from the plurality of EMG sensors.

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13. Apparatus according to claim 12, wherein the controller is configured so that the amplitude of NMES stimulation of each of said plurality of muscles or muscle parts depends at least partly on the EMG signal from the corresponding muscle or muscle part.

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14. Apparatus according to any of the preceding claims, wherein the paretic body part is a body part that comes in pairs.

15. Apparatus according to claim 14, wherein the paretic body part is an arm.

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16. Apparatus according to claim 14, wherein the paretic body part is a leg.

17. Apparatus according to any of claims 14-16, wherein the healthy body part belongs to the patient.

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18. Apparatus according to any of claims 14-16, wherein the healthy body part belongs to a different person.

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19. Apparatus according to any of the preceding claims, wherein the controller makes the stimulation amplitude at least partly dependent on a processed form of the EMG signal.

20. Apparatus according to claim 19, wherein the processed form of the EMG signal is stretched out in time from the EMG signal.

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21. Apparatus according to claim 19 or claim 20, wherein the processed form of the EMG signal corresponds to an EMG signal that would be produced by a movement of the healthy body part that is a mirror image of a movement that the healthy part was undergoing when the EMG signal was generated.

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22. Apparatus according to any of claims 19-21, wherein the processed form of the EMG signal is time delayed from the EMG signal.

23. Apparatus according to any of the preceding claims, also including a first position sensing device which monitors a position of the healthy body part.

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24. Apparatus according to claim 23, also including a first actuating device which mechanically changes the position of the healthy body part.

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25. Apparatus according to any of the preceding claims, also including a second position sensing device which monitors a position of the paretic body part.

26. Apparatus according to any of claims 1-25, including a paretic actuating device which 5 mechanically changes the position of the paretic body part under control of said controller and according to said expected move.

27. Apparatus according to claim 24, wherein said first actuating device mechanically changes the position of said healthy body part at varying levels chosen from the group of 10 complete assistance, partial assistance or no assistance.

28. Apparatus according to claim 24, wherein said first actuating device mechanically changes the position of said healthy body part by limiting the range of motion of said part.

15 29. Apparatus according to claim 26, wherein said second actuating device mechanically changes the position of said paretic body part at varying levels chosen from the group of complete assistance, partial assistance or no assistance.

20 30. Apparatus according to claim 26, wherein said second actuating device mechanically changes the position of said paretic body part by limiting the range of motion of said part.

31. Apparatus comprising a controller, and a neuromuscular electrical stimulation (NMES) device, the controller storing (i) patient class, and (ii) a desired motion of the paretic body part, and being adapted to determine an amplitude of stimulation of the paretic body part at least 25 partly based on said storage such that said NMES amplitude is not sufficient, on its own, to cause said desired motion but is sufficient to cause said desired motion when a patient in said class attempts to move the body part at the same time; and the NMES device being adapted to provide a stimulation of the determined amplitude.

30 32. Apparatus according to any of the preceding claims, also including at least one paretic EMG sensor adapted for applying to a voluntary muscle of the paretic body part, which at least one paretic EMG sensor produces at least one paretic EMG signal.

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33. Apparatus according to claim 32, wherein the controller makes the amplitude of stimulation of the paretic body part at least partly dependent on the at least one paretic EMG signal.

5 34. Apparatus according to claim 33, wherein the at least one paretic EMG sensors adapted for applying to the paretic body part comprise a plurality of paretic EMG sensors, each adapted for being applied to a different muscle or muscle part of the paretic body part, and each producing a separate paretic EMG signal.

10 35. Apparatus according to claim 34, wherein the NMES device is adapted to stimulate the muscles or muscle parts of the paretic body that the paretic EMG sensors are adapted for being applied to, and the controller is configured to make the amplitude of stimulation of each muscle or muscle part depend at least partly on the paretic EMG signal from that muscle or muscle part.

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36. A method of rehabilitating a patient who has a paretic body part, the method comprising:

- a) having the patient or another person move a healthy body part that is of the same type as the paretic body part;
- 20 b) detecting EMG signals from the healthy body part while it is being moved;
- c) processing said EMG signals to determine at least one property of a NMES signal;
- d) applying a NMES signal to the paretic body part, responsive to said processing; and
- e) moving said paretic body part at most partially by said NMES stimulation.

25 37. A method according to claim 36, wherein said NMES is applied at a timing according to said EMG signals.

38. A method according to claim 36, wherein said NMES is applied at an amplitude according to said EMG signals.

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39. A method according to claim 36, also including having the patient attempt to move the paretic body part, while the NMES is applied, in the same pattern of movement that the healthy body part is moved in while the EMG signals are detected.

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40. A method according to claim 39, wherein detecting the EMG signals comprises detecting the EMG signals from a plurality of muscles or muscle parts of the healthy body part, and applying NMES comprises applying NMES to a plurality of muscles or muscle parts of the paretic body part corresponding to the plurality of muscles or muscle parts of the
5 healthy body part.

41. A method according to claim 40, wherein the amplitude of NMES applied to each muscle or muscle part of the paretic body part during a time interval in the pattern of attempted movement of the paretic body part depends at least partly on the EMG signal detected from the corresponding muscle or muscle part of the healthy body, during a corresponding time interval in the pattern of movement of the healthy body part.
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42. A method according to any of claims 36-41, wherein the paretic body part is mechanically provided with movement by an actuating device.
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43. A method according to claim 42, wherein said actuating device is synchronized to said detected EMG.

44. A method according to claim 42, wherein said actuating device is synchronized to said
20 applied NMES.

45. A method according to any of claims 36-44, wherein the paretic body part is mechanically assisted with movement by an actuating device.
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46. A method according to any of claims 36-45, wherein movement of the paretic body part is limited by an actuating device.

47. Apparatus according to any of claims 1-35, wherein said desired motion is of an arm.

30 48. A method according to any of claims 36-45, wherein said paretic body part is an arm.